BERNSTEIN LIEBHARD & LIFSHITZ, LLP
Keith M. Fleischman (KF-0199)
Robert J. Berg (RB-8542)
Felecia L. Stern (FS-3431)
Ronald J. Aranoff (RA-4690)
10 East 40th Street
New York, New York 10016
Telephone: (212) 779-1414

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LORRAINE KOPA, on Behalf of Herself and all Others Similarly Situated, Plaintiff, v. PFIZER, INC. and WARNER LAMBERT COMPANY, Defendants.	**CIVIL ACTION NO.** **CLASS ACTION COMPLAINT FOR VIOLATIONS OF 18 U.S.C SECTIONS 1962 ET SEQ., BREACH OF IMPLIED WARRANTY, UNJUST ENRICHMENT AND NEGLIGENCE** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiff Lorraine Kopa, by her attorneys, brings this action on behalf of herself and all other persons similarly situated in the United States and alleges upon information and belief, formed after an inquiry reasonable under the circumstances, except as to those allegations which pertain to the named plaintiff or to her attorneys (which are alleged on personal knowledge), hereby alleges as follows:

INTRODUCTION

1. This class action is brought against Defendants Pfizer, Inc. ("Pfizer") and the Warner-Lambert Company ("Warner") (collectively "Defendants") for violations of the civil Racketeer Influenced and Corrupt Organization Act (18 U.S.C §1962 *et seq.*) and for breach of implied warranty, unjust enrichment, and negligence to recover for the harm caused by Defendants' illegal marketing scheme designed to push and promote "off-label" uses of the prescription drug Neurontin. ("Off-label" is the term describing uses for a drug that are not approved by the U.S. Food and Drug Administration ("FDA")).

2. Defendants, like other drug companies, spend billions of dollars each year trying to persuade doctors to prescribe their particular drugs. There are, however, strict FDA regulations about what form that promotion may take. These rules and requirements are meant to ensure that drug companies provide physicians and medical personnel reliable information, so that medications are properly prescribed. As described below, Defendants intentionally violated these rules in order to increase their profits.

3. In 1993, Defendants received FDA approval to market and sell Neurontin, in certain doses, for the treatment of epilepsy. The market for this treatment, however, was relatively small. Based on limited anecdotal evidence, Defendants believed that Neurontin could also be used to treat other diseases and ailments. The market for these off-label uses was enormous. Motivated by a desire to avail themselves of this enormous market, starting as early as 1995, Defendants embarked on a course of conduct to increase Neurontin's off-label sales. Specifically, Defendants decided to bypass the normal FDA regulatory process pertaining to the marketing of a new use for a drug and to proceed expeditiously in an illegal manner. Moreover,

Defendants also decided to actively conceal the illegal means by which Neurontin would now be marketed.

4. Ultimately, Defendants' actions proved successful as profits from Neurontin sales between 1995 and 2003 rose from $97.5 million to approximately $2.7 billion, due mostly to off-label sales. Approximately 90% of all Neurontin prescriptions were, and currently are, written for off-label purposes.

5. Defendants' scheme, as set forth below, ultimately tricked physicians and consumers into believing that prescribing and taking Neurontin for the off-label uses that Defendants promoted was appropriate even though Defendants knew FDA approval had not been granted and that there was little – if any – scientific evidence suggesting Neurontin was safe and effective when so used.

6. Indeed, the United States Attorney for the District of Massachusetts brought criminal charges against Defendants for this conduct. The attorneys general for many of the 50 states also commenced litigation against the Defendants under the relevant consumer protection statute of those states. On May 13, 2004, Defendants agreed to plead guilty to federal criminal charges and simultaneously entered into a settlement agreement with the attorneys general.

PARTIES

7. Plaintiff Lorraine Kopa is a resident of Carbondale, Pennsylvania. In November 2003, Plaintiff was prescribed and purchased the drug Neurontin for the treatment of severe back pain.

8. Defendant Pfizer is a Delaware corporation maintaining its principal place of business in New York. Pfizer is principally engaged in the manufacture and sale of

pharmaceuticals. In 2000, Pfizer merged with Defendant Warner-Lambert and created the present day company. Defendant Warner-Lambert manufactured, marketed and sold the drug Neurontin through its Parke-Davis division during the relevant time period.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §1331 because Plaintiff's claims arise under the laws of the United States in that Plaintiff alleges violations of the RICO Act, 18 U.S.C. §1962 *et seq.*

10. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. §1367.

11. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because Pfizer's principal place of business is within the Southern District of New York and a substantial part of the events giving rise to Plaintiff's claims occurred in the Southern District of New York.

FACTUAL ALLEGATIONS

A. FDA Regulations

12. FDA regulations require any pharmaceutical company to seek and obtain FDA approval before any new drug may be marketed. Once approval is granted, a drug may only be promoted for the approved use at the approved dose.

13. Physicians, however, may still prescribe drugs for unapproved uses. These uses are deemed off-label because they have not been approved by the FDA. A pharmaceutical company is permitted to disseminate certain information about off-label uses, but such dissemination must adhere to strict requirements. For instance, the manufacturer must submit an application to the FDA seeking approval of the drug for off-label use; the manufacturer must

provide the materials it plans to use to market the drug for off-label uses to the FDA prior to dissemination; the materials must be in unabridged form; and the manufacturer must include disclosures that the materials pertain to an unapproved use of the drug, and, if the FDA deems it appropriate, "additional objective and scientifically sound information . . . necessary to provide objectivity and balance." Food and Drug Administration Act of 1997, 21 U.S.C. §360aaa, *et seq.* The dissemination of information in violation of these provisions violates the Food, Drug and Cosmetic Act. 21 U.S.C. §331(z).

14. Although these requirements permit pharmaceutical companies to disseminate to physicians and other health care practitioners qualified forms of written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug, 21 U.S.C. §360aaa(a), manufacturers are permitted to provide only authorized information in the form of unabridged peer-reviewed articles or qualified reference publications. *Id.* §360aaa-1. This law also requires pharmaceutical companies to furnish federal regulators with advance copies of the information they disseminate. 21 U.S.C. §360aaa. Any deviation from these requirements violates FDA regulations.

B. Neurontin and the Off-Label Marketing Scheme

15. In December 1993, the FDA approved Neurontin as "adjunctive therapy" for the treatment of certain types of seizures in adult patients suffering from epilepsy. "Adjunctive therapy" means that the drug could not be prescribed by itself for the treatment of epilepsy, but as an add-on drug in the event that a primary anti-epilepsy drug was not successful. The FDA approved labeling of Neurontin and stated that the drug is only effective at dosages ranging from 900 to 1800 mg/day.

16. The Defendants' original patent on Neurontin was set to expire in December 1998. This meant that Defendants had exclusive rights to the drug for a mere 5 years. After the expiration of the Neurontin patent, Defendants would be forced to share the market for Neurontin with generic drug manufacturers. This would substantially reduce Defendants' profits and their ability to keep Neurontin's retail price high.

17. At the time Defendants filed their New Drug Application ("NDA") with the FDA, Defendants intended Neurontin to be used for other indications besides epilepsy adjunctive therapy. In the early to mid 1990's, Defendants filed patents for Neurontin claiming it to be effective in the treatment of depression, neurogenerative disease, mania, bipolar disease and for anxiety and panic. Notably, the market for these uses of Neurontin was much larger than the market for epilepsy.

18. Early on, Defendants intended to file supplemental NDAs in order to expand Neurontin's approved indications, including applications for monotherapy and for the above-mentioned psychiatric and neurological indications. However, by 1995, Defendants came to the conclusion that it would be uneconomical to assume the expense necessary to conduct clinical trials necessary to prove that Neurontin was safe and effective for these uses. Assuming Neurontin could be proved to be safe and effective, the near term expiration of the patent meant that generic manufacturers of Neurontin would reap much of the reward that comes with proving Neurontin could be safely used for other indications.

19. After performing extensive economic analysis, senior officials for Defendants determined that it was not sufficiently profitable for Defendants to obtain FDA approval for Neurontin's alternative uses. Instead, Defendants' officials developed a strategy that would allow Defendants to avoid the costs of proving that Neurontin was safe and effective for these other

uses, while allowing Defendants to compete in the lucrative off-label markets. As one aspect of the scheme, Defendants decided to employ a "publication strategy" that would allow it to promote Neurontin by the massive distribution of publications supposedly written by independent researchers that purportedly described the scientific evaluation of Neurontin. An advantage of this strategy, from Defendants' perspective, was that it could be employed immediately – there was no need to wait for the results of scientifically conducted clinical trials to determine if Neurontin was actually effective in the treatment of these conditions.

20. As set forth above, federal regulations did not permit Defendants to promote unapproved uses of Neurontin. Defendants were allowed, however, to distribute publications created by independent "third parties" that described results of off-label uses of Neurontin as long as these materials were given in response to unsolicited requests from physicians. Defendants exploited this narrow exception by creating events and programs that would allow their employees and independent contractors to promote off-label uses under circumstances that would allow Defendants the chance to deny, wrongfully, that they had actually promoted and solicited off label usage.

21. Marketing executives at Parke-Davis headquarters in Morris Plains, New Jersey and in its five regional customer business units ("CBUs") selected a marketing strategy which would deliberately lead to increased off-label usage of Neurontin even though Defendants knew that they could not promote Neurontin lawfully for non-approved uses. These executives knew that Defendants were not supposed to create or design the contents of the communications that would be distributed pursuant to the "publication strategy" or do anything to generate the practicing physicians' interest in receiving such communications. As demonstrated below, however, Defendants ignored these legal requirements and, instead, put into effect a pervasive

pattern of illegal conduct, lasting from at least 1994 through 1998, and Plaintiff believes, to the present.

22. Significant ingenuity and resourcefulness was necessary in order to execute this unlawful scheme without detection. Faced with the fact that its "publication strategy" required publications from independent physicians when no such publications existed, Defendants hired non-physician technical writers to create articles for medical journals and then paid actual specialists to be the articles' "authors." Faced with the fact that their normal marketing force could not deliver the off-label message, Defendants trained their "medical liaisons," technical employees who were supposed to provide balanced scientific information to doctors, to sell off-label and solicit interest in off-label uses.

23. In order for a publication strategy to actually increase usage of a drug, Defendants had to have a large group of doctors interested in experimenting on patients, and an even larger group of doctors who were interested in receiving information about those experiments. Defendants generated both groups by liberally distributing payments to both groups of physicians through "consultants" meetings, speakers bureaus, medical education seminars, grants, "studies," advisory boards and teleconferences.

24. Defendants carried out this scheme through the following, among other things:

- illegal kickbacks to physicians who prescribed large amounts of Neurontin for off-label purposes to Plaintiff and the class;
- the formation of a nationwide network of employees falsely referred to as "medical liaisons" whose actual assigned duties consisted entirely of conventional direct sales activities and which did not include any legitimate scientific activity;
- the illegal direct solicitation of physicians for off-label uses;
- the making of false statements to physicians and pharmacists concerning the efficacy and safety of Neurontin for off-label uses;

- the payment or offering of gratuities to Defendants' employees in order to procure their silence; and

- the active training of Defendants' employees in methods of avoiding detection of their activities by the FDA.

C. Defendants Used "Medical Liaisons" To Promote Off-Label Use

25. Pursuant to federal regulations, Defendants' usual sales force was not permitted to promote off-label uses of Neurontin to their physician customers. The FDA, however, permitted drug company representatives to provide balanced, truthful information regarding off-label usage if (1) specifically requested by a physician and (2) if there was no attempt to solicit such information by the drug company.

26. Beginning in 1995, Defendants increasingly hired "medical liaisons" and trained them to aggressively solicit requests for off-label information from physicians. Once this door was open, Defendants trained these medical liaisons to engage in full scale promotion of Neurontin's off-label uses, including repetitive distribution of non-scientific, anecdotal information designed to convince physicians that off-label usage of Neurontin was safe and effective. In effect, Defendants used the medical liaisons as a surrogate sales force that had liberty to solicit physicians regarding off-label uses. Indeed, medical liaisons were selected and promoted based largely on their ability to sell. Moreover, aggressive sales training was encouraged.

27. Defendants knew their use of these medical liaisons was unlawful, but continued the practice. In fact, Dr. David Franklin, a whistleblower in a *qui tam* action, was told by Defendants that the use of medical liaisons were disguised ways of getting around the FDA rules.

28. Moreover, on April 16, 1996, at a training session for medical liaisons, Defendants' in-house lawyers stopped the video taping of a medical liaison training session to advise the liaisons that notwithstanding formal policies to the contrary, liaisons could "cold call" on physicians so long as they had executed request forms, i.e. forms that supposedly verified that the physician had initiated the meeting, at the end of the call. The liaisons were informed that the request forms could be filled out by Defendants sales' representatives instead of the doctors. Company lawyers also informed the liaisons in training that there was no need to present balanced information to the customers and those liaisons should always remember that sales were necessary in order to keep the company profitable. The liaisons were also informed by the lawyers, off camera, that there really was no definition of "solicitation" and that there were methods to induce the physicians to inquire about off-label uses. In effect, once the medical liaison got a meeting with a doctor, there were ways to get the information about off-label uses to the doctor even if the physician had not actually requested off-label information. The lawyers also warned the liaisons under no circumstances should any information about off-label uses be put in writing.

29. Medical liaisons were instructed in the clearest possible terms that they were to market and sell Neurontin based on its off-label uses. For example, on a teleconference on May 24, 1996, John Ford, a senior marketing executive at Defendants' Morris Plains location directly informed the medical liaisons that in order to market Neurontin effectively, Neurontin had to be marketed for monotherapy, pain, bipolar disorder, and other psychiatric uses, all of which were off-label. Ford conceded that such marketing had to be primarily performed by the medical liaisons, because they were the only ones who could discuss these matters. At another meeting with the medical liaisons, Ford was even more straightforward. He said:

> I want you out there every day selling Neurontin. Look this isn't just me, it's come down from Morris Plains that Neurontin is more profitable...We all know Neurontin's not growing adjunctive therapy, beside that is not where the money is. Pain management, now that's money. Monotherapy, that's money. We don't want to share these patients with everybody, we want them on Neurontin only. We want their whole drug budget, not a quarter, not half, the whole thing....We can't wait for them to ask, we need to get out there and tell them up front...That's where we need to be holding their hand and whispering in their ear, Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for everything...I don't want to see a single patient coming off Neurontin until they have been up to at least 4800 mg/day. I don't want to hear that safety crap either, have you tried Neurontin, every one of you should take one just to see there is nothing, it's a great drug.

30. Medical liaisons were trained with a "pitch" to cold call physicians who saw the most patients in a given specialty, and sell them on the off-label benefits of Neurontin. A key aspect of this scheme was misrepresentation. The first misrepresentation was usually the status of the medical liaisons as they, with the full approval of Defendants' marketing officials such as John Ford, Phil Magistro, and John Krukar, were routinely introduced as specialists in the specific drug they were presenting at a particular meeting. Medical liaisons were also encouraged to represent themselves as medical researchers, even though they neither conducted medical research nor analyzed medical research performed by others. It was also not uncommon for medical liaisons to be introduced as physicians, even though they had no such qualifications.

31. Other aspects of this pitch (labeled the "Neurontin Cold Call Story") included:

- Mention that you are the eyes and ears of Defendants' research and that you are gathering clinical info;
- Then ask general questions about the nature of the practice;
- Mention Neurontin and its approved uses, but dismiss them as old news;
- Ask leading questions about the number of pain patients that the practice sees;
- Then ask a series of questions that determine the practice profile for all of the potential off-label uses;

- Next reveal that Defendants have "a great deal of information about the fantastic response rate of patients on Neurontin in all of these disease states";
- Move into a discussion of the clinical trials that this information is demanding;
- And the "90-95% response rate that we are seeing in more than 80% of patients";
- Present the doctor with any publications that are available and point out that many common drugs for pain treatment are in few if any publications;
- Ask the physician to place some patients on Neurontin and tell them that the medical liaison will stay in touch to help develop any case reports;
- Mention that case reports can be lucrative and can lead to clinical trials;
- Offer to do a presentation and luncheon for the entire practice or a group of his friends that will detail all of the "data" we have;
- Invite the physician to consultant meetings in the future and point out that they pay $250 plus a nice trip or meal in the city; and
- If a sales representative is present they should close the sale by asking that the next patient he sees should be put on Neurontin.

32. During a training session for medical liaisons, Dr. David Franklin first witnessed the scope of the off-label claims that Defendants intended to use to market Neurontin. The medical liaisons were provided with new company slides that detailed the methods used to increase the use of Neurontin in several different off-label practice types. The slide show contained a slide that showed the "Anecdotal Uses of Neurontin" including reflex sympathetic dystrophy, peripheral neuropathy, diabetic neuropathy, trigeminal neuralgia, post-herpetic neuralgia, trigeminal neuralgia, post-Herpetic neuralgia, essential tremor, restless leg syndrome, attention deficit disorder, periodic limb movement disorder, migraine, bipolar disorder, Lou Gehrig's Disease, and drug or alcohol withdrawal seizures.

33. Defendants' executives explained that "this list was very important to the company but that it makes Neurontin look like snake oil, so preempt the laughter by telling your

physicians that, 'I'm embarrassed to show you the next slide because it makes Neurontin look like snake oil, but the fact is, we are seeing extra-ordinary results, in some cases up to 90% response in all of these conditions, that will get their attention.'" Richard Grady, a medical liaison, asked if "we have any money to lace studies without big docs." He was instructed to "use the potential of a study to get in the door, even get protocols, but don't waste too much time and don't say you can get them a study, we don't have much money left." He was then told that "if anyone asks for back-up data say we are pulling it together, then suggest that the doc put some of his patients on Neurontin and we will help him publish case reports that could help place a study in his practice. Everybody wins."

34. Importantly, none of the off-label claims made in the slide had been substantiated, let alone approved, by the FDA.

35. Defendants also made extensive misrepresentations regarding the scientific information concerning off-label usage of Neurontin. According to Dr. Franklin, the following misrepresentations relating to off-label usage of Neurontin were routinely made to physicians with Defendants' knowledge and consent:

- **Bipolar Disorder:** Medical liaisons informed psychiatrists that early results from clinical trials evaluating Neurontin for the treatment of bipolar disorder indicated a ninety percent (90%) response rate when Neurontin was started at 900 mg/day dosage and increased to a dosage of 4800 mg/day. No such results existed. Nor was any type of clinical trial being conducted other than a pilot study. There were no clinical trials or studies indicating that Neurontin was safe or effective up to 4800 mg/day. Indeed, Defendants were in possession at this time of clinical trial evidence which showed that there was no dose response difference between patients who received 600 mg/day, 1200 mg/day and 2400 mg/day. Any data relating to the use of Neurontin in bipolar disorder was strictly anecdotal and of nominal scientific value. Indeed, most of the published reports on this topic had been written and commercially sponsored by Defendants, although this fact was hidden.

- **Peripheral Neuropathy, Diabetic Neuropathy, and Other Pain Syndromes:** Medical liaisons were trained and instructed to report that "leaks" from clinical trials demonstrated that Neurontin was highly effective in the treatment of various pain syndromes and that a ninety percent (90%) response rate in the treatment of pain was being reported. No such body of evidence existed. Nor was there any legitimate pool of data from which a response rate, much less a ninety percent (90%) response rate, could be calculated. Medical liaisons were trained to claim support for these findings as a result of inside information about clinical trials where no such information existed. The only support for these claims was anecdotal evidence of nominal scientific value. Many of the published case reports had been created and/or sponsored by Defendants in articles which frequently hid Defendants' involvement in the creation of the article. Defendants' payment for the creation of these case reports was also hidden from physicians.

- **Epilepsy Monotherapy:** Medical liaisons were strongly encouraged to push neurologists to prescribe Neurontin as the sole medication to treat epilepsy, even though studies only found it safe and effective as adjunctive therapy. Medical liaisons were trained to inform neurologists that substantial evidence supported Defendants' claim that Neurontin was effective as monotherapy. In fact, at this time, Defendants knew that clinical trials regarding Neurontin's efficacy as a monotherapy were inconclusive. One of Defendants' clinical trials demonstrated that Neurontin was not an effective monotherapy agent; the vast majority of patients in the study taking Neurontin were unable to continue with Neurontin alone. The same study showed that there was no effective difference between administration of Neurontin at 600, 1200 or 2400 mg. Notwithstanding this data, Defendants continued to claim that physicians should use Neurontin as substantially higher doses than indicated by the labeling. Indeed, although medical liaisons routinely claimed Neurontin to be effective as monotherapy, in 1997 the FDA refused to find Neurontin safe and effective as monotherapy.

- **Reflex Sympathetic Dystrophy ("RSD"):** Medical liaisons informed physicians that extensive evidence demonstrated the efficacy of Neurontin in the treatment of RSD. The only such evidence that existed was anecdotal reports of nominal scientific value. Medical liaisons were trained to refer to case reports, most of which had been created or sponsored by Defendants, as "studies."

- **Attention Deficit Disorder ("ADD"):** Medical liaisons were instructed to inform pediatricians that Neurontin was effective for the treatment of ADD. No data, other than occasional anecdotal evidence, supported this claim. Nonetheless, the medical liaisons were trained to report that large number of physicians had success treating ADD with Neurontin, when no such case reports existed.

- **Restless Leg Syndrome ("RLS"):** RLS was another condition where Defendants' medical liaisons were trained to refer to a growing body of data

relating to the condition, when no scientific data existed. The only reports were anecdotal, most of which had been created and/or sponsored by Defendants.

- **Trigeminal Neuralgia:** Although medical liaisons represented that Neurontin could treat Trigeminal Neuralgia, again no scientific data supported this claim with the exception of occasional anecdotal reports. No data demonstrated that Neurontin was as effective as currently available pain killers, most of which were inexpensive.

- **Post-Herpatic Neuralgia ("PHN"):** Medical liaisons were trained to tell physicians that seventy-five percent (75%) to eighty percent (80%) of all PHN patients were successfully treated with Neurontin. Once again, no clinical trial data supported such a claim.

- **Essential Tremor Periodic Limb Movement Disorder:** Medical liaisons were trained to allege that Neurontin was effective in the treatment of these conditions. No scientific data supported such claims with the exception of anecdotal reports of nominal scientific value.

- **Migraine:** Claims that Neurontin was effective in the treatment of migraine headaches were made by the medical liaisons and were supposedly based on early results from clinical trials. Although pilot studies had been suggested and undertaken, no early results of clinical trials existed to support these claims. Once again, any data relating to treatment of migraines was purely anecdotal and of nominal scientific value. Most of the case reports were either created or sponsored by Defendants.

- **Drug and Alcohol Withdrawal Seizures:** Medical liaisons suggested that Neurontin be used in the treatment of drug and alcohol withdrawals despite the lack of any data supporting Neurontin as an effective treatment for these conditions.

36. Defendants knew and intended for physicians to rely on these misrepresentations. These physicians did so and consequently provided inaccurate and untruthful medical advice to their patients. Regardless, Defendants' personnel routinely made these misrepresentations as part of company policy. Along with Dr. Franklin, some of the other physicians who were lied to were Michael Davies, Joseph McFarland, Phil Magistro, Lisa Kellett, Joseph Dymkowski, Darly Moy, Richard Grady, Ken Lawler, and many others.

37. Dr. Franklin also reported that Defendants were guilty of the following conduct:

- Upon order of the company and as a result of training of medical liaisons, Dr. Franklin "deliberately contrived reports to mislead physicians into believing that a body of data existed that demonstrated the effectiveness of Neurontin in the treatment of bipolar disease." In fact, no data existed at all to support the use of Neurontin in bipolar disease.

- Dr. Franklin was trained and instructed to actively deceive physicians with contrived data, falsified "leaks" from clinical trials, scientifically flawed reports, or "success stories" that stated that Neurontin was highly effective in the treatment of a variety of pain syndromes. No such body of evidence existed.

- He was instructed to advise physicians that Defendants had developed a large body of data to support the use of Neurontin as monotherapy. This was an "outright lie" and left patients unknowingly without good seizure control.

- Medical liaisons were instructed to tell physicians that a great deal of data existed that supported the safe use of Neurontin at levels that exceed 4800 mg/day. However, clinically significant safety data existed at dosing levels at only 1800 mg/day.

- Defendants provided medical liaisons with slides that stated that Neurontin was effective for the treatment of Attention Deficit Disorders but no data existed to support that claim.

D. <u>Defendants' Illegal Payments to Doctors</u>

38. Defendants' "publication strategy" required physicians and the "medical liaisons" to perform the work normally performed by the company's salesmen in order to promote Neurontin. Adoption of the "publication strategy" required Defendants to make thousands of payments to physicians for the purpose of having those doctors either recommend the prescription of Neurontin or to actually order Neurontin in violation of federal kickback regulations. Defendants were aware that these regulations were violated routinely by their employees. The following describes the various programs Defendants used to make these payments to physicians:

1. Consultants' Meetings

39. Defendants used "consultants' meetings" to make illegal payments to physicians to encourage off-label use of Neurontin. Federal rules prohibit "kickbacks" to physicians and medical care providers in exchange for prescribing a particular drug. Defendants disguised their kickbacks as "consultantships."

40. Under this guise, Defendants recruited physicians to dinners or conferences and paid them to hear presentations about off-label uses of Neurontin. Under the fiction that these doctors were acting as consultants, Defendants sometimes (but not always) had the doctors sign sham consulting agreements. At these meetings, Defendants would give these doctors lengthy presentations relating to Neurontin, particularly regarding off-label usage. Presentations would be made by Defendants' employees or physician speakers hired by Defendants for the purpose of promoting Neurontin, and attendees' questions relating to the administration of Neurontin use would be solicited and answered. At some conferences, the sponsoring organization or Defendants intentionally posed questions to the speakers about off-label use to insure that attendees were exposed to such information.

41. At some, but not all, "consultants' meetings" a few questions would be posed to the "consultants" regarding Defendants' marketing of Neurontin or how Defendants sales force could provide better service to the doctors. The consultants' meetings, however, were not held, and the consultants were not paid, for the purpose of providing Defendants with expert, independent advice. Defendants in many cases did not even record the "advice" provided by its consultants and what advice was collected was never acted upon or reviewed.

42. Defendants did, however, routinely analyze whether the consultants' meetings were successful in getting the attendees to change their prescription writing practices. At some

meetings, the consultants were directly asked if they would write more Neurontin prescriptions as a result of the meeting. Such a question would have been irrelevant if the actual purpose of the meeting was to receive the consultants' advice. Defendants also routinely tracked consultants' Neurontin prescription writing practices after these meetings. Using market data purchased from third parties, Defendants analyzed whether the doctors they had paid had in fact written more Neurontin prescriptions after the meeting. Again, such data was only relevant if the real purpose of the payments was to influence the doctors to order more Neurontin.

43. A typical consultants' meeting was held in Jupiter Beach, Florida for neurologists from the North East CBU during the weekend of April 19-21, 1996. The "consultants" selected for this meeting were not chosen on the basis of their consulting acumen, but because of their potential to write Neurontin prescriptions. In a memorandum announcing the event to Defendants' personnel, the "Neurontin Marketing Team" acknowledged that in order to target neurologists with the greatest potential for writing Neurontin prescriptions, sales personnel must select potential attendees from a list of top prescription writers for anti-epileptic drugs in the Northeast; only persons who fell within this desirable demographic were allowed to be invited.

44. Qualifying physicians were given round-trip airfare to Florida (worth $800.00), two nights accommodations (worth $340.00), free meals and entertainment, ground transportation and a "consultant's fee" of $250.00. Ample time was provided so that Defendants' consultants could enjoy the beach resort. The value of the junket was approximately $2,000.00 per physician.

45. The Jupiter Beach consultants meeting included two half days of presentations by Defendants relating to Neurontin, including extensive presentations relating to off-label uses. Although technically the presentations were provided by an independent company, Proworx, all

aspects of the presentation were designed, monitored, and approved by Defendants. Defendants selected the speakers, picked the presentation topics and previewed the content of the presentations to make sure that they were acceptable. Defendants paid all expenses relating to the consultants' meeting including all payments to the attendees and the presenters, all travel, accommodation, meals and entertainment expenses, all presentation expenses, all expenses and fees incurred by Proworx, and the substantial fees paid to the presenting physicians. Notwithstanding the FDA's prohibition regarding the provision of promotional materials on off-label uses, Defendants provided written abstracts of the presentations that detailed off-label use of Neurontin to each of its "consultants."

46. Defendants made no effort to obtain professional advice at Jupiter Beach from the consultants Defendants had wined, dined, and entertained during the weekend. A follow-up memorandum to Defendants' marketing officials noted that "the participants were delivered a hard hitting message about Neurontin" and emphasized that the participants were encouraged to use Neurontin at higher doses. More importantly, after the conference, Defendants generated "trending worksheets" listing the doctors who attended the consultants' meeting. These worksheets enabled Defendants to track Neurontin prescription habits of the attendees before and after the consultants' meetings to determine if these "high writing" prescribers wrote more Neurontin prescriptions after the conference. Persuading these heavy prescribers to order more Neurontin for their patients was, in fact, the sole purpose of the Jupiter Beach junket.

47. Jupiter Beach was not unique. Defendants hosted dozens of consultants' meetings between late 1995 and 1997 in which the consultants received payments and gratuities as well as presentations on off-label Neurontin use designed to change the physicians' prescription writing habits. Comparable consultants' meeting included, but were not limited to the following:

Topic	Location	Dates
Mastering Epilepsy	La Costa Resort, CA	July 20-23, 1995
Mastering Epilepsy	Santa Fe, NM	Nov. 16-19, 1995
Neurontin Consultants Conference	Marco Island, FL	February 2-4, 1996
Pediatric Epilepsy	Hutchinson Island, FL	February 9-11, 1996
Mastering Epilepsy	Walt Disney World, FL	February 22-25, 1996
Pediatric Epilepsy	Hutchinson Island, FL	March 8-10, 1996
Mastering Epilepsy	Ritz Carlton, Aspen, CO	April 18-21, 1996
Affective Disorders in Psychiatry	Marco Island, FL	April 20, 1996
Affective Disorder Consultants Conference	Southern Pines, NC	April 27, 1996
Neuropathic Pain Conference	Palm Beach, FL	May 11, 1996
Regional Consultants Conference	Ritz Carlton, Boston, MA	May 10-11, 1996
Epilepsy Management Advisors Meeting	Sheraton Grande Torrey Pines, La Jolla, CA	June 21-23, 1996
Epilepsy Management	Rancho Bernardo, CA	June 28-30, 1996
Use of Anti-Convulsants in Psychiatric Disorders	Short Hills, NJ	October 18-19, 1996
Non-epileptic Uses of Neurontin	Longboat Key, FL	Nov. 6, 1996
Neurological Conditions Conference	Ritz Carlton, Atlanta, GA	Sept. 27-28, 1997

Other "consultants" meetings took place at Charleston, SC, Coconut Grove, FL, Naples, FL, Memphis, TN, Louisville, KY, Washington, D.C., Aspen, CO, and other places. Hundreds, if not thousands, of physicians received kickbacks to attend those events.

48. Not all payments to consultants were made at conferences as elaborate as Jupiter Beach. Many such meetings consisted of expensive dinners at local restaurants. The emphasis on these meetings was also on off-label uses, and $200 "honorariums" were paid to the physicians who did nothing for the payment except show up. At none of the events did the consultants provide legitimate consultation to Defendants, but at all of the events the consultants were encouraged to increase their Neurontin prescription writing.

2. Medical Education Seminars

49. Another format where Defendants paid kickbacks to physicians to hear off-label promotion of Neurontin were programs billed as Continuing Medical Education seminars ("CME"). These conferences and seminars were set up to appear to qualify for an exception to the FDA's off-label marketing restrictions which permits physicians to learn about off-label uses of pharmaceuticals at independent seminars. Such seminars, however, must be truly independent of the drug companies. The drug companies may make "unrestricted grants" for the purpose of a seminar, but may not be involved in formulating the content of the presentations, picking the speakers or selecting the attendees. None of these requirements were observed with regard to the CME seminars sponsored by Defendants for the promotion of off-label uses of Neurontin. While Defendants retained third party organizations, such as Proworx and MES, to present the event seminars, it had control of virtually every aspect of these events, and the seminar companies obtained Defendants' approval for all content presented at the seminars. Defendants also paid all expenses, including all the seminar companies' fees.

50. Although the seminar companies acted as the conduit for the payments and gratuities given to the physician attendees, like the Jupiter Beach consultants' meetings, Defendants controlled every aspect of the CME programs. Defendants designed and approved the programs; hand-picked the speakers for the seminars; approved the presentations at the seminars; previewed, in most cases, the contents of the seminars prior to delivery, selected the attendees based on their ability and willingness to prescribe high quantities of Neurontin; evaluated the presentations to make sure Defendants' "message" was appropriately delivered; black-listed presenters whose presentations were not sufficiently pro-Neurontin; and monitored the prescribing patterns of the physicians who attended these conferences to insure the purpose

of the conference – increased writing of Neurontin prescriptions – was achieved. Follow-up reports to marketing executives for Defendants highlighted that the attendees received presentations regarding off-label marketing and recommendations for dosages larger than those labeled effective by the FDA. These memoranda also reported to senior executives the pledges made by attendees to order more Neurontin for their patients.

51. For some seminars, high prescription writing physicians were selected to receive junkets comparable to those Defendants provided to the attendees of the Jupiter Beach "consultants" meetings. Others were less lavish, but physicians received free tuition, free accommodations, free meals, and cash. Frequently, the Defendants' CME seminars were accredited by continuing medical education organizations, which meant that the physicians taking advantage of Defendants' junkets did not have to pay tuition or spend additional time to fulfill their continuing medical education licensure requirements by attending truly independent medical education programs.

52. Representative CME programs sponsored by Defendants where they paid extensive kickbacks to attending physicians, included, but are not limited to, the following:

Seminar	Location	Dates
Merritt-Putnam Epilepsy Postgraduate Course	unknown	January 19, 1996
Merritt-Putnam Seminar	Chicago, IL	January 26, 1996
New Frontiers in AntiEpileptic Drug Use	California	Sept-Oct 1996
Diabetic Neuropathy	Ritz Carlton, Boston, MA	June 22-24, 1997
Merritt-Putnam Symposium	Key Biscayne, FL	September 11, 1997
Merritt-Putnam Conference on Monotherapy	Palm Springs, CA	September 9, 1997
Merritt-Putnam Conference on Monotherapy	St. Louis, MO	October 3, 1997
Merritt-Putnam Symposium	Boston, MA	December 5, 1997

3. Grants and "Studies"

53. Defendants also made outright payments, in the form of grants, to reward demonstrated Neurontin believers and advocates. Defendants' sales managers identified key doctors who actively prescribed Neurontin or programs which were willing to host Neurontin speakers and encouraged such persons or programs to obtain "educational grants" from Defendants. Under this program of kickbacks Defendants paid:

- $2,000.00 to Berge Ninmpolan, MD, "a great Neurontin believer," to attend a neurology seminar in San Francisco, in March 1996;
- $1,000.00 to the University of Texas at Houston, Department of Neurology to host a symposium where presentations would be made regarding successful off-label treatment with Neurontin;
- $3,000.00 to the University of Texas Medical School to host a conference in August 1996 at which a well known specialist in epilepsy, who prescribed Neurontin, would attend;
- $4,000.00 to pay for a neurologist from the University of Texas at San Antonio to attend the American Epilepsy Society Conference in December 1996, a conference at which Defendants was presenting extensive documentation on off-label uses for Neurontin;
- $2,500.00 to the University of Texas at Houston to bring Dr. B.J. Wilder to the campus to hold a seminar. Dr. Wilder was one of Neurontin's biggest boosters for off-label indications and had been paid tens of thousands of dollars to promote Neurontin's off-label uses for Defendants across the country;
- $2,500.00 in June 1996 to pay for representatives from the University of Pennsylvania Medical Center to attend a conference in Saint Petersberg, Russia on the utilization of anti-epileptic drugs, including Neurontin;
- $5,000.00 to Dr. Alan B. Ettinger, of Stony Brook, NY in December 1996, a physician who had informed Defendants that he was interested in possibly doing research in Neurontin and maintained a database of patients who were treated with Neurontin;
- $500.00 to Bruce Ehrenberg, of Boston, MA, a leading speaker for Defendants regarding off-label uses of Neurontin, to attend a conference in China;

- $1,000.00 to Israel Abrams, M.D., Paul C. Marshall, M.D., Beth Rosten, M.D. and Spencer G. Weig, M.D., of Worcester, MA, for educational programs in February 1996. According to the local Defendants' representative requesting the grant, "much of the Neurontin success in Worcester has been attributed to...the 4 pediepileptologists below.";

- $1,400.00 to Dr. Ahmad Beydoun of Ann Arbor, MI for post-graduate training in March 1996. This grant was processed on a quick turnaround, the Defendants representative noting "I realize that this is a very short time line; however, Dr. Beydoun is a very important customer.";

- $1,500.00 to Jim McAuley, Ph, Ph.D. for educational materials relating to epilepsy. Defendants decided to provide the funds because McAuley was an advocate of Neurontin and he was important in getting another Defendants' drug, Cerebyx, accepted on the formulary for Ohio State University; and

- A grant in an unknown amount to University Hospital in Cleveland in exchange for hosting programs regarding Neurontin's use in treating neuropathic pain at conferences specifically devoted to obtaining referrals from other doctors.

54. These grants, and others, were charged to the Neurontin marketing budget. Each of these grants was made solely because an individual who would receive the money was a large Neurontin supporter or would host a program where a well-known Neurontin supporter would recommend that other physicians increase their prescriptions of Neurontin. Each of these grant awards constituted a reward or kickback for the recipient's advocacy of Neurontin.

55. Defendants' medical liaisons informed leading Neurontin subscribers that significant advocacy for Neurontin would result in the payment of large grants. Specifically, the liaisons would suggest that the doctors participate in articles or studies regarding the benefits of Neurontin. These studies did not involve significant work for the physicians. Often they required little more than collating and writing up office notes or records. Indeed, as noted below, Defendants frequently hired technical writers to write the articles for which the "authors" had been given grants.

56. Defendants were aware that these articles and studies provided minimal scientific benefit. In a letter to the FDA in June 1997, Defendants submitted a list of "studies relating to pain, pain syndromes, and psychiatric disorders" which failed to include any of these numerous studies, purportedly funded by Defendants. Defendants intentionally neglected to report these "studies" to the FDA and concealed these "studies" from the FDA because they knew the funded "research" had no scientific value and would not be deemed to be studies by the FDA. Payments Defendants made for "studies" included, but were not limited to the following:

Funded Project	Payee	Payment
Statistical Analysis of Patients Treated With Neurontin For Pain	Hans Hansen, M.D.; Statesville, NC	$7,000.00
Reduction of Sympathetically Medicated Pain and Sudomotor Function	David R. Longmire, M.D.; Russellville, AL	$7,000.00
Data Entry for Neurontin And Pain Analysis	Travis Jackson, M.D., David Meyer, M.D.; Winston-Salem, NC	unknown
Trial of Neurontin for distal symmetric polyneuropathy associated with AIDS	Joseph Weissman, M.D. Atlanta, GA	$20,000.00
Neurontin for neuropathic Pain in chronic pain syndromes	Lavern Brett, M.D. Washington, D.C.	$25,000.00
Retrospective chart analysis of Neurontin use with bipolar disorder Patients	Ralph S. Rybeck, M.D.	$5,000.00
Retrospective Analysis of Neurontin in the treatment of pain	David R. Longmire, M.D.; Russellville, AL	$2,000.00
Retrospective Analysis of Neurontin in the treatment of chronic pain	Don Schanz, D.O. Traverse City, MI	$8,000.00
Case histories relating to use of Neurontin as an adjuvant analgesic	Elizabeth J. Narcessian, M.D.; W. Orange, NJ	$4,000.00

Plaintiff has reason to believe that other payments were made to physicians for other "studies" of questionable scientific credibility.

57. One particularly large study conducted by Defendants served as yet another engine to financially reward physicians for prescribing Neurontin. In 1995 and 1996, Defendants conducted an enormous Phase IV trial known as STEPS. Although STEPS took the form of a research clinical trial, it was, in fact, a marketing ploy designed to induce neurologists to become comfortable prescribing Neurontin at a far higher dose than indicated in the FDA approved labeling. While most clinical studies have a limited number of investigators treating a number of patients qualified for the study, the STEPS protocol called for over 1,200 "investigators" to enroll only a few patients each. The participating physicians were instructed to titrate their patients to higher than labeled dosages of Neurontin to demonstrate that patients could tolerate high dosages of the drug. Rewarding physicians for prescribing high doses of Neurontin was another way to increase Neurontin sales because higher per patient dosages increased the amount of Neurontin sold. Additionally, the STEPS study was also designed to habituate physicians to place non-study patients on Neurontin on doses higher than found effective in the clinical trials monitored by the FDA.

58. Physicians enrolling in the STEPS study were paid for agreeing to participate in the study and for every patient enrolled. At the conclusion of the study, Defendants offered each of the 1,200 investigators additional cash for each patient the doctor kept on Neurontin after the study ended. These payments were unquestionably kickbacks as each participating doctor was expressly paid for writing Neurontin prescriptions for their patients. The number of investigators who received such payments are too many for Plaintiff to list. Additionally, Defendants have exclusive control of the information regarding who received such payments at the conclusion of the STEPS trial.

4. Payments to "Authors" of Ghost Written Articles

59. Yet another method of rewarding doctors for their advocacy of Neurontin was to pay them honorarium for lending their names to scientific articles which were actually prepared and written by third parties retained by Defendants. In 1996, Defendants retained AMM/ADELPHI, Ltd. ("AMM") and Medical Education Systems, Inc., ("MES") to prepare no less than twenty (20) articles for publication in various neurology and psychiatry journals. Most of these articles concerned off-label usage of Neurontin and were generated so that Defendants would have completely controlled publications they could distribute pursuant to their "publication strategy." The content of these articles were actually written by non-physician technical writers retained by Defendants, and Defendants had the right to control the content of all the articles. Defendants paid all expenses in connection with the creation of these publications.

60. Once Defendants and the technical writers conceived the articles, Defendants and their outside firms attempted to find recognized Neurontin prescribers whose names could be used as the authors of these articles. In some cases, drafts of the articles were completed even before an "author" agreed to place his or her name on the article. This even occurred in connection with case histories that purported to describe the "author's" personal treatment of actual patients. The "authors" were paid an honorarium of $1,000.00 to lend their names to these articles, and also were able to claim publication credit on their curriculum vitae.

61. Defendants and their outside firms found journals that would publish the articles. Defendants' role in creating, approving and sponsoring the articles was hidden from the public. While the articles might reference that the author received an honorarium from the outside firm, the articles failed to state that the honorarium was paid with money provided by Defendants and

that Defendants had approved the content and hired the actual authors. For example, an article created by Medical Education Systems (MES), *Gabapentin and Lamotrignine: Novel Treatments for Mood and Anxiety Disorders*, published in CNS Spectrums, noted that "an honorarium was received from Medical Education Systems for preparation of this article," but never revealed Defendants' retention and payment of MES or the fact the MES personnel, while under contract to Defendants, wrote the article.

62. Defendants used these publications as part of their publication strategy by presenting the articles as evidence of independent research conducted by persons with no monetary interest in Neurontin. This impression, of course, was false. Defendants created the articles to promote off-label uses for Neurontin, purchased the names and reputations of the authors with kickbacks and controlled the content of the articles.

5. Speakers' Bureau

63. Defendants also founded the Speakers' Bureau, another method to make large and numerous payments to physicians who recommended Neurontin at teleconferences, dinner meetings, consultants' meetings, educational seminars, and other events. These speakers repeatedly gave short presentations relating to Neurontin for which they were paid anywhere from $250.00 to $3,000.00 per event. Speakers such as Steven Schachter, B.J. Wilder, Ilo Leppik, Gary Mellick, David Longmire, Gregory Bergey, Michael Merren, David Treiman, Michael Sperling, Martha Morrell, R. Eugene Ramsay, John Pellock, Ahmad Beydoun, Thomas Browne, John Gates, Jeffrey Gelblum, Dennis Nitz, Robert Knobler and others received tens of thousands of dollars annually in exchange for recommending to fellow physicians that Neurontin be prescribed, particularly for off-label uses. The payments that these doctors received were far in excess of the fair market value of the work they performed for Defendants. Speakers who

most zealously advocated Neurontin were hired most frequently for speaking events, notwithstanding the fact that many of these events purported to be independent medical education seminars where independent information was supposed to be delivered. The identity of the doctors in the Speaker's Bureau who received kickbacks through excessive compensation can only be determined after review of the records in the exclusive custody of the Defendant.

64. Defendants' marketing personnel, including its medical liaison staff, informed physicians of the lucrative rewards of joining the Neurontin Speaker's Bureau. Physicians were informed that if they prescribed enough Neurontin, they, too, could also be eligible for receiving substantial payments just for describing their clinical experience to peers at events dedicated to promoting Neurontin's off-label uses. Defendants' marketing personnel, however, made it clear that the only way the doctors could receive such cash payments was if they prescribed substantial amounts of Neurontin to their patients, preferably for off-label uses.

65. Defendants either knew that the payments described above constituted kickbacks or acted in reckless disregard of federal laws and regulations that prohibit such kickbacks. They also knew that federal safe harbors did not cover the extensive payments they made to doctors. Moreover, Defendants were aware that their payments did not comply with the AMA's guidelines for payments to physicians. Nonetheless, Defendants did nothing to curb their kickback payments to physicians and could not have marketed Neurontin's "off-label" uses without such payments.

66. In 1997, in the wake of an investigation by the FDA, Defendants conducted a review of their marketing practices in light of existing Federal kickback regulations. As a result of that review, Defendants determined that none of the programs described above should have been conducted in the manner previously conducted by Defendants. Defendants issued

guidelines to comply with the Federal regulations which essentially prohibited each of the programs described above. Nonetheless, the payments to physicians for the off-label marketing of Neurontin did not cease and the programs continued at least until 1998. Defendants' records demonstrate payments of inappropriate kickbacks to doctors through 1998, and perhaps up to the guilty plea in May, 2004.

CLASS ACTION ALLEGATIONS

67. Plaintiff brings this class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a general class (the "Class") consisting of:

> All persons and entities in the United States that have purchased the prescription medication, Neurontin, after being prescribed said medication for medical conditions other than those conditions for which Neurontin was approved by the U.S. Food and Drug Administration during the period January 1, 1994 to the present (the "Class Period").

68. Excluded from the Class are: (I) all present and former authorized agents and spouses of such authorized agents of Defendants; (ii) all present and former employees and spouses of such employees of Defendants; (iii) any Class member who timely elects to be excluded from the Class; and (iv) all members of the judiciary of this Court and their immediate families.

69. The proposed Class is sufficiently definite so that it is administratively feasible to determine whether a particular individual is a member. Also, the proposed Class consists of thousands of members, and therefore, is so numerous that joinder is impractical.

70. Plaintiff's claims are typical of the claims of the Class because Plaintiff, like all Class members, purchased Neurontin for an off-label use not approved by the FDA.

71. There are questions of law and fact common to the Class which include, but are not limited to:

(a) Whether Defendants developed and carried out a uniform national pattern of conduct whereby physicians and consumers were duped into believing the off-label uses promoted by Defendants were approved by the FDA;

(b) Whether Defendants knew or should have known that Neurontin was not approved by the FDA for purposes other than as a secondary drug for the treatment of epilepsy;

(c) Whether Defendants intentionally misrepresented the intended and approved uses of Neurontin through employees and "medical liaisons" employed to promote off-label uses for Neurontin;

(d) Whether Defendants knew or were reckless in not knowing the nature and condition of the products sold to the consuming public;

(e) Whether Defendants embarked on an illegal scheme to provide kickbacks to physicians prescribing large amounts of Neurontin for off-label purposes to Plaintiff and members of the Class;

(f) Whether Defendants negligently, recklessly or intentionally, concealed the intended use of Neurontin from Plaintiff and members of the Class;

(g) Whether Defendants negligently, recklessly or intentionally made false statements to physicians and pharmacists concerning the efficacy and safety of Neurontin for off-label uses;

(h) Whether Defendants acted negligently at the expense of Plaintiff and the Class;

(i) Whether Defendants' conduct has resulted in unjust enrichment at the expense of Plaintiff and the Class;

(j) Whether Defendants' conduct has resulted in a breach of implied warranty;

(k) Whether Defendants' conduct has resulted in a violation of the RICO Act, 18 U.S.C. §1962 *et seq.*;

(l) Whether Defendants' conduct constitutes fraudulent concealment;

(m) Whether Plaintiff and Class members are entitled to compensatory and punitive damages, and the amount of such damages; and

(n) Whether Plaintiff and Class members are entitled to equitable, declaratory and injunctive relief.

72. These common issues of law and fact predominate over individual issues pertaining to individual Class members and class certification is a superior method of resolving those claims.

73. Plaintiff will fairly and adequately represent and protect the interests of the Class. Plaintiff is a member of the Class and is willing to serve as representative of the Class. Plaintiff has retained counsel with substantial experience in prosecuting nationwide consumer class actions. Plaintiff and Plaintiff's counsel are committed to vigorously prosecuting this action on behalf of the Class.

74. Class certification pursuant to F.R.C.P. 23(B)(2) is appropriate because Defendants' course of dealing with members of the Class adversely affects all members of the Class, thereby making appropriate final and injunctive relief corresponding to declaratory relief

with respect to the Class as a whole, whereby Defendants would be compelled to cease such course of dealing.

75. Class certification pursuant to F.R.C.P. 23(B)(3) is appropriate because a class action is superior to all other available methods for the fair and efficient adjudication of this controversy and the questions of law or fact common to the members of the Class predominate over any questions affecting only individual Class members. Moreover, the damages suffered by individual Class members are small compared to the burden and expense of individual prosecution of the litigation needed to address Defendants' conduct. Further, it would be virtually impossible for the members of the Class individually to effectively redress the wrongs that they have individually suffered. Even if Class members themselves could afford such individual litigation, the court system could not, given the size of the Class. In addition, individualized litigation increases the delay and expense to all parties and to the court system. Individualized litigation also presents a potential for inconsistent or contradictory judgments. By contrast, class litigation presents far fewer management difficulties, allows adjudication of claims that might otherwise go unaddressed because of the expense of bringing individual litigation, and provides the benefits of uniform adjudication, economies of scale, and comprehensive supervision by a single court.

THE ROLE OF THIRD PARTIES IN DEFENDANTS' MARKETING SCHEME

76. Various physicians, vendors and other Third Parties (collectively "Third Parties") played important roles in Defendants' overall marketing plan. These Third Parties knowingly and intentionally, communicated and distributed the misrepresentations concerning off-label uses of Neurontin. For instance, non-physician writers generated inaccurate and unscientific articles

pertaining to the safety and efficacy of Neurontin. Certain physicians then loaned their names-and thereby became authors-to these articles. Other physicians participated in so called "studies" that misrepresented facts and evidence pertaining to Neurontin.

77. The vendors, AMM and MES, published these articles in medical journals across the nation.

78. These Third Parties were participants in Defendants' marketing scheme and were conscious of, and participated in, the illegal scheme. They also operated collectively, for a common purpose, and as a continuing unit to perpetuate Defendants' scheme.

79. The Third Parties' knowledge, involvement, and activity is exhibited by (1) the failure to alert physicians, patients, FDA officials, or consumers about the spread of misinformation concerning off-label uses; (2) their acceptance of incentives in exchange for supporting, authoring, or publicizing the above described misrepresentations knowing physicians and consumers would rely on these misrepresentations; and (3) their agreement to permit Defendants to control the information relayed to the public in the articles.

WARNER LAMBERT'S PLEA OF GUILTY TO THE FEDERAL INFORMATION CHARGING CRIMINAL VIOLATIONS OF THE FOOD, DRUG AND COSMETIC ACT

80. On May 13, 2004, Warner Lambert was charged with criminal violations of the Federal Food, Drug and Cosmetic Act in an information brought by the Department of Justice in the United States District Court for the District of Massachusetts.

81. The information presented criminal charges against Warner Lambert for violations of 21 U.S.C. 331(a) and (d), 333(a)(2), 352(f)(1) and 355(a) based upon the misconduct set forth above.

82. The information charged that Warner Lambert violated 21 U.S.C. 331(a) and (d) by introducing and distributing Neurontin into interstate commerce for uses other than its approved uses and by introducing and delivering Neurontin into interstate commerce in violation of 21 U.S.C. 355, which required Warner Lambert to obtain FDA approval for all of the proposed intended uses of Neurontin .

83. The information further charged that Warner Lambert violated 21 U.S.C. 352(f) (1) by misbranding Neurotin without adequate directions in its label for its proper use.

84. The information further charged that Warner Lambert violated 21 U.S.C 355(a) by introducing and delivering Neurontin into interstate commerce without applying for and obtaining FDA approval for Neurontin's proposed and intended uses.

85. Warner Lambert entered a plea of guilty to all of the above-referenced criminal charges immediately upon the filing of such charges.

USE OF THE MAILS AND WIRES

86. During the Class Period, Defendants used thousands of mail and interstate wire communications to create and manage their fraudulent scheme. Defendants' scheme involved national marketing and sales plans and programs, and encompassed physicians and victims across the country. Defendants' use of the mails and wires to perpetrate their fraud involved thousands of communications throughout the Class Period, including:

- marketing and advertising materials about the off-label uses of Neurontin for which the drug is not safe and medically efficacious, such materials being sent to doctors across the country;
- communications, including financial payments, with the Vendors, AMM and MES, non-physician technical writers, and physician "authors" discussing and relating to the publication of articles touting off-label uses of Neurontin for which the drug is not safe and medically efficacious;

- communications with the Vendors and physicians that fraudulently misrepresented that Neurontin was scientifically proven to be safe and effective for off-label uses;

- communications with patients and consumers, including Plaintiff and the Class, inducing payments for Neurontin to be made in reliance on misrepresentations concerning the use of Neurontin for non-medically necessary uses; and

- receiving the proceeds of the Defendants' improper scheme.

87. In addition, Defendants' corporate headquarters have communicated by United States mail, telephone, and facsimile with various local district managers, medical liaisons and pharmaceutical representatives in furtherance of Defendants' scheme.

COUNT ONE

VIOLATION OF 18 U.S.C. § 1962(c) - MES ENTERPRISE

88. Plaintiff incorporates the allegations contained in the preceding paragraphs.

89. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. §1962(c).

90. The "MES Enterprise" is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of each Defendant, including their employees and agents, and MES. The MES Enterprise is an ongoing organization that functions as a continuing unit. The MES Enterprise was created and/or used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the MES Enterprise.

91. The MES Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided Neurontin to thousands of individuals throughout the United States.

92. Defendants have exerted control over the MES Enterprise, and Defendants have participated in the operation or management of the affairs of the MES Enterprise, through the following actions:

- Multiple instances of selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States;
- Defendants have asserted direct control over the information and content disseminated to the Vendors (including MES), physicians and the public regarding the medical safety and efficacy of Neurontin for off-label uses in articles published across the country;
- Defendants have asserted direct control over the creation and distribution of mass-marketing and sales materials sent to Vendors and physicians through the United States; and
- Defendants have placed their own employees and agents in positions of authority and control in the MES Enterprise.

93. Defendants have conducted and participated in the affairs of the MES Enterprise through a pattern of racketeering activity by selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States, as set forth in the information and guilty plea described above, as well by acts indictable under 18 U.S.C. §§ 1341 and 1343 (mail and wire fraud), as described above.

94. In implementing their fraudulent scheme, Defendants were acutely aware that Plaintiff and members of the Class depend on the honesty of Defendants in representing the safety and medical efficacy of Neurontin's uses.

95. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) causing providers to misrepresent the off-label use(s) for which Neurontin was being prescribed so that Plaintiff and members of the Class were unaware that contrary to their plain language they were purchasing Neurontin for off-label uses; (b) deliberately misrepresenting the uses for

which Neurontin was safe and effective so that Plaintiff and members of the Class paid for this drug to treat symptoms for which it was not scientifically proven to be safe and effective; (c) publishing or causing to have published materials containing false information upon which physicians, Plaintiff, and members of the Class relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses for which the drug is not scientifically proven to be safe or medically efficacious; and (d) actively concealing, and causing others to conceal, information about the true safety and efficacy of Neurontin to treat conditions for which it had not been approved by the FDA.

96. Defendants' scheme was calculated to ensure Plaintiff and the Class would pay for Neurontin to treat a wide variety of uses which Defendants knew were not necessarily treatable with Neurontin.

97. Each of Defendants' acts involved in the selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States and Defendants' fraudulent mailings and interstate wire transmissions constitute "racketeering activity" within the meaning of 18 U.S.C. § 961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. §1961(5).

98. Defendants engaged in a pattern of racketeering activity intending to defraud Plaintiff and the Class.

99. The above described racketeering activities amounted to a common course of conduct intended to deceive Plaintiff and the Class. Defendants' criminal acts of racketeering had the same pattern and similar purpose of defrauding Plaintiff and the Class. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff

and the members of the Class. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to the property of Plaintiff and the Class.

100. The pattern of racketeering activity alleged herein and the MES Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the MES Enterprise.

101. Plaintiff and members of the Class have been injured in their property because Plaintiff and members of the Class have made billions of dollars in payments of Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

102. Plaintiff and members of the Class relied to their detriment on Defendants' fraudulent misrepresentations and omissions.

103. Plaintiff and members of the Class' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

104. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the cost of this suit, including reasonable attorneys' fee.

COUNT TWO

VIOLATION OF 18 U.S.C. § 1962(c) – AMM ENTERPRISE

105. Plaintiff incorporates the allegations contained in the preceding paragraphs.

106. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

107. The "AMM Enterprise" is an association-in-fact within the meaning of 18 U.S.C. §1961(4), consisting of each of Defendants, including their employees and agents, and AMM.

The AMM Enterprise is an ongoing organization that functions as a continuing unit. The AMM Enterprise was created and/or used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the AMM Enterprise.

108. The AMS Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided Neurontin to thousands of individuals throughout the United States.

109. Defendants have exerted control over the AMM Enterprise, and Defendants have participated in the operation or management of the affairs of the AMM Enterprise, through the following actions:

- Multiple instances of selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States;
- Defendants have asserted direct control over the information and content disseminated to the Vendors (including AMM), physicians and the public regarding the medical safety and efficacy of Neurontin for off-label uses in articles published across the country;
- Defendants have asserted direct control over the creation and distribution of mass-marketing and sales materials sent to Vendors and physicians through the United States; and
- Defendants have placed their own employees and agents in positions of authority and control in the AMM Enterprise.

110. Defendants have conducted and participated in the affairs of the AMM Enterprise through a pattern of racketeering activity by selling or otherwise dealing in dangerous drug in a manner punishable under the laws of the United States, as set forth in the information and guilty plea described above, as well by acts indictable under 18 U.S.C. §§1341 and 1343 (mail and wire fraud), as described above.

111. In implementing their fraudulent scheme, Defendants were acutely aware that Plaintiff and members of the Class depend on the honesty of Defendants in representing the safety and medical efficacy of Neurontin's uses.

112. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) causing providers to misrepresent the off-label use(s) for which Neurontin was being prescribed so that Plaintiff and members of the Class were unaware that contrary to their plain language they were purchasing Neurontin for off-label uses; (b) deliberately misrepresenting the uses for which Neurontin was safe and effective so that Plaintiff and members of the Class paid for this drug to treat symptoms for which it was not scientifically proven to be safe and effective; (c) publishing or causing to have published materials containing false information upon which physicians, Plaintiff, and members of the Class relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses for which the drug is not scientifically proven to be safe or medically efficacious; and (d) actively concealing, and causing others to conceal, information about the true safety and efficacy of Neurontin to treat conditions for which it had not been approved by the FDA.

113. Defendants' scheme was calculated to ensure the Plaintiff and the Class would pay for Neurontin to treat a wide variety of uses which Defendants knew were not necessarily treatable with Neurontin.

114. Each of Defendants' acts involved in the selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States and Defendants' fraudulent mailings and interstate wire transmissions constitute "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

115. Defendants engaged in a pattern of racketeering activity intending to defraud Plaintiff and the Class.

116. The above described racketeering activities amounted to a common course of conduct intended to deceive Plaintiff and the Class. Defendants' criminal acts of racketeering had the same pattern and similar purpose of defrauding Plaintiff and the Class. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the members of the Class. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to the property of Plaintiff and the Class.

117. The pattern of racketeering activity alleged herein and the AMM Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the AMM Enterprise.

118. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have made billions of dollars in payments of Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

119. Plaintiff and members of the Class relied to their detriment on Defendants' fraudulent misrepresentations and omissions.

120. Plaintiff's and members of the Class' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

121. By virtue of these violations of 18 U.S.C. §1962(c), Defendants are jointly and severally liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the cost of this suit, including reasonable attorneys' fee.

COUNT THREE

VIOLATION OF 18 U.S.C. § 1962(c) – GROUP ENTERPRISE

122. Plaintiff incorporates the allegations contained in the preceding paragraphs.

123. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

124. The "Group Enterprise" is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Pfizer and Warner-Lambert, including their employees and agents, and the non-physician writers, physician "authors" and Vendors located throughout the United States who participated in the fraudulent schemes described above. The Group Enterprise is an ongoing organization and functions as a continuing unit. The Group Enterprise was created and/or used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the Group Enterprise.

125. The Group Enterprise falls within the meaning of 18 U.S.C. § 1961(4), and consists of a group of "persons" associated together for the common purposes of marketing and selling Neurontin to Plaintiff and the Class and earning profits therefrom.

126. The Group Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided Neurontin to thousands of individuals throughout the United States.

127. Defendants have exerted control over the Group Enterprise, and Defendants have participated in the operation or management of the affairs of the Group Enterprise, through the following actions:

- Multiple instances of selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States;
- Defendants have asserted direct control over the information and content disseminated to doctors and the public regarding the medical safety and efficacy of Neurontin for off-label uses in articles published across the country.
- Defendants have asserted direct control over the creation and distribution of mass-marketing and sales materials sent to doctors through the United States; and
- Defendants have placed their own employees and agents in positions of authority and control in the Group Enterprise.

128. Defendants have conducted and participated in the affairs of the Group Enterprise through a pattern of racketeering activity by selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States, as set forth in the information and guilty plea described above, as well by acts indictable under 18 U.S.C. §§1341 and 1343 (mail and wire fraud), as described above.

129. In implementing their fraudulent scheme, Defendants were acutely aware that Plaintiff and members of the Class depend on the honesty of Defendants in representing the safety and medical efficacy of Neurontin's uses.

130. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) causing providers to misrepresent the off-label use(s) for which Neurontin was being prescribed so that Plaintiff and members of the Class were unaware that contrary to their plain language they were purchasing Neurontin for off-label uses; (b) deliberately misrepresenting the uses for which Neurontin was safe and effective so that Plaintiff and members of the Class paid for this drug to treat symptoms for which it was not scientifically proven to be safe and effective; (c) publishing or causing to have published materials containing false information upon which physicians, Plaintiff, and members of the Class relied upon when choosing to prescribe or pay

for Neurontin to treat off-label uses for which the drug is not scientifically proven to be safe or medically efficacious; and (d) actively concealing, and causing others to conceal, information about the true safety and efficacy of Neurontin to treat conditions for which it had not been approved by the FDA.

131. Defendants' scheme was calculated to ensure the Plaintiff and the Class would pay for Neurontin to treat a wide variety of uses which Defendants knew were not necessarily treatable with Neurontin.

132. Each of Defendants' acts involved in the selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States and Defendants' fraudulent mailings and interstate wire transmissions constitute "racketeering activity" within the meaning of 18 U.S.C. §1961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. §1961(5). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. §1961(5).

133. Defendants engaged in a pattern of racketeering activity intending to defraud Plaintiff and the Class.

134. The above described racketeering activities amounted to a common course of conduct intended to deceive Plaintiff and the Class. Defendants' criminal acts of racketeering had the same pattern and similar purpose of defrauding Plaintiff and the Class. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the members of the Class. Defendants' fraudulent activities as part of their ongoing business and constitute a continuing threat to the property of Plaintiff and the Class.

135. The pattern of racketeering activity alleged herein and the Group Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the Group Enterprise.

136. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have made billions of dollars in payments of Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

137. Plaintiff and members of the Class relied to their detriment on Defendants' fraudulent misrepresentations and omissions.

138. Plaintiff's and members of the Class' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

139. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the cost of this suit, including reasonable attorneys' fee.

COUNT FOUR

VIOLATION OF 18 U.S.C. § 1962(d) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962 (c)

140. Plaintiff incorporates the allegations contained in the preceding paragraphs.

141. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

142. Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly,

the conduct of the affairs of the § 1962(c) Enterprises described previously through a pattern of racketeering activity.

143. As demonstrated in detail above, Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff and the Class of money.

144. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. §1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

145. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. §1962(d) by conspiring to violate 18 U.S.C. §§1962(c), Plaintiff and the Class have been and continue to be injured in their business or property as set forth more fully above.

146. Defendants have sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

- Multiple instances of selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States;
- Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;
- Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and

147. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1343 and 1346.

148. Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and will continue unless injunctive relief prohibiting Defendants' illegal acts constituting a pattern of racketeering activity is fashioned and imposed by the Court.

COUNT FIVE

BREACH OF THE IMPLIED WARRANTY

149. Plaintiff incorporates the allegations contained in the preceding paragraphs.

150. Defendants have breached the implied warranty of merchantability in that Neurontin was not reasonably fit for the off label purposes for which it was sold, intended, or reasonably foreseen, to be used. Moreover, the Neurontin manufactured and sold by Defendants was defective on the date of its delivery to Plaintiff and the Class.

151. Defendants have also breached the implied warranty of fitness for a particular purpose. Neurontin is not reasonably fit for the specific off label purposes for which Defendants knowingly sold it and for which the Plaintiff and Class bought Neurontin in reliance on Defendants.

152. Plaintiff and the Class have suffered damages as a result of Defendant's breach of warranty.

COUNT SIX

UNJUST ENRICHMENT

153. Plaintiff incorporates the allegations contained in the preceding paragraphs.

154. By means of the conduct described above, Defendants have knowingly received, and continue to receive, a substantial benefit at the expense of Plaintiff and Class members.

155. It would be unjust and unconscionable to permit Defendants to enrich themselves at the expense of Plaintiff and Class members and to retain the funds that Defendant wrongfully obtained from Plaintiff and Class members.

COUNT SEVEN

NEGLIGENCE

156. Plaintiff incorporates the allegations contained in the preceding paragraphs.

157. Defendants have a duty to exercise the necessary degree of care expected and required of manufacturers of health care products. Defendants deviated from that duty by promoting the off-label uses of Neurontin.

158. As a result of Defendants' negligence, Plaintiff and the Class have been injured. These damages are the actual and proximate result of Defendants' breach of this duty of care.

FRAUDULENT CONCEALMENT/
EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

159. Any applicable statutes of limitation have been tolled by Defendants' affirmative acts of deliberate and fraudulent concealment. Through such acts, Defendants have been able to conceal from Plaintiff and the Class the truth about Defendants' practice of falsely representing the approved uses of Neurontin, thereby tolling the running of the applicable statutes of limitation.

160. Plaintiff and the Class could not reasonably have discovered Defendants' wrongful conduct as alleged herein.

161. Defendants are estopped from relying on any statute of limitations defense because of their unfair or deceptive conduct.

162. Until shortly before the filing of this Complaint, Plaintiff had no knowledge that Defendants were engaged in the wrongful conduct alleged herein.

163. Because of the self-concealing nature of Defendants' actions, and its affirmative acts of concealment, Plaintiff asserts the tolling of any applicable statutes of limitations affecting his claims.

PRAYER FOR RELIEF

WHEREFORE, on behalf of herself and the members of the Class, Plaintiff prays for judgment and relief against all Defendants, jointly and severally, as follows:

A. An Order certifying this action as a class action as defined herein;

B. An Order appointing Plaintiff and her counsel to represent the Class;

C. An award of monetary damages, the amount of which to be proven at trial and statutory damages, as well as equitable, injunctive and declaratory relief;

D. Reasonable attorneys' fees, costs, expenses and disbursements of suit;

E. Pre- and post-judgment interest; and

F. Such other and further relief as this Court may deem necessary, proper and/or appropriate.

JURY DEMAND

Plaintiff respectfully demands a trial by jury as to all causes of action so triable.

DATED: June 18, 2004

BERNSTEIN LIEBHARD & LIFSHITZ, LLP

By _____

Keith M. Fleischman (KF-0199)
Robert J. Berg (RB-8542)
Felecia L. Stern (FS-3431)
Ronald J. Aranoff (RA-4690)
10 East 40th Street
New York, NY 10016
Tel: (212) 779-1414

Attorneys for Plaintiff